OWNER'S MANUAL

Alpha-Stim®100

Microcurrent & Cranial Electrotherapy Stimulator

for control of pain, anxiety, depression, and insomnia

Type B Equipment. This stimulator is internally powered only.

See Instructions for use.
Read this manual thoroughly before using. Do not plug lead wires into wall sockets or line cord receptacles under any circumstances. Doing so could result in severe shock or burns whether the lead wires are attached to the stimulator or not.

Medical Electrical Equipment classified by Underwriters Laboratories Inc.® with respect to electric shock, fire, mechanical and other specified hazards only in accordance with UL-2601-1 and CAN/CSA C22.2 No. 601.1. 34VF.

Conformity Statement for Europe:
The Alpha-Stim® 100 is a Class IIa, Type B medical device. It has been independently tested by outside agencies in order to provide assurance of conformity to applicable standards for medical equipment safety and electromagnetic compliance.

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Alpha-Stim® is registered in the US Patent and Trademark office and worldwide.

CONTENTS

Introduction……4

Description……4

Electromedical Therapeutics……5

How To Use The Alpha-Stim®100 For Pain Control……6

Sample Protocols……11

How To Use The Alpha-Stim®100 For Anxiety, Depression and/or Insomnia Control……12

Skin Care……13

What to Expect……13

Prescribing Information: Indications, Contraindications, Precautions, Adverse Effects……14

Technical Specifications……14

Storage and Cleaning……15

Trouble Shooting……15

Service……16

5 Year Limited Warranty……16

A NOTE TO DOCTORS

Thank you for recommending the Alpha-Stim® 100. This manual is written for the person who will be using the Alpha-Stim® 100, but your input will be invaluable to your patient. One way to help is to explain to your patient exactly where his or her problem is located, along with any corresponding areas (such as the low back in the case of leg pain). You might suggest specific electrode locations for your patient's particular problem. Alpha-Med is available to serve the needs of your patients, and to support you in doing so. New research is constantly available that may have a direct bearing on one of your patient's specific disorders. Feel free to write, call, fax, or email Alpha-Med for any reason at all.

INTRODUCTION

Congratulations on your selection of the Alpha-Stim® 100 microcurrent electrical therapy (MET) and cranial electrotherapy stimulation (CES) device. You have purchased a quality medical instrument. In so doing, you have already taken the first step to a more comfortable and rewarding life.

Alpha-Med was established with the aim of improving the quality of our Clients' lives and we are dedicated to help those who use our products. We have technical experts available to assure that you receive the best possible support. Telephone consultations can be scheduled with you and your doctor, Sunday through Thursday, 10 a.m to 5 p.m. You may also communicate with us by mail, fax or email. We stand behind all our Alpha-Stim Stimulators with the manufacturer's 5 year warranty as indicated in this manual.

The Alpha-Stim® 100 is a precision medical instrument used for the management of pain, anxiety, depression, and/or insomnia. This treatment is non-invasive and drug-free. The Alpha-Stim® 100 provides a welcome alternative to drugs, especially in disorders that require long-term management. Unlike some drugs, the Alpha-Stim® 100 leaves the mind alert. The dangerous side effects of drugs are avoided, including accidental, intentional, and/or suicidal overdosing. After treatment, there are usually no physical limitations imposed so you can resume normal activities. The treatment is simple and can easily be self-administered at any time. People using the Alpha-Stim® 100 usually report a pleasant relaxed feeling of well-being.

The current is applied by easy-to-use self-adhesive electrodes or hand-held probes for pain control or by ear clip electrodes for anxiety, depression, and/or insomnia. During a treatment you may experience a mild tingling sensation as a result of the stimulating current flow.
The Alpha-Stim® 100 is often the only means required to relieve pain, anxiety, depression, and/or insomnia. However, it may also be added to other therapy prescribed by your doctor. The Alpha-Stim® 100 will not interfere with most other treatments.

Once you understand the basic procedures, you will find the Alpha-Stim® 100 is very easy to use. Please read this entire manual thoroughly before using it. Be sure to follow the general instructions given herein, and any specific directions from your doctor.

DESCRIPTION

The Alpha-Stim® 100 was developed through original research by Electromedical Products International, Inc. in Texas, USA. It is a precision technology which generates a modified square, bipolar waveform of 0.5, 1.5, or 100 pulses per second (Hz), 10 to 600 millionths of an ampere (μA), at a 50% duty cycle.

The Alpha-Stim® 100 is small, compact and light-weight. Its design lends itself well to treatment in a health practitioner's office, clinic or hospital as well as self-administered treatment at home. The controls are simple and easy to operate. An adjustable interval timer assures the prescribed treatment time even if you are distracted or fall asleep. The amount of current can be easily modified for maximum comfort and effectiveness.

The Alpha-Stim® 100 may be categorized into 2 general categories.

Microcurrent electrical therapy, or MET, is a term used to describe a low level current used for pain control applied through easy-to-use probes, or self-adhesive electrodes. It is distinguished from previous forms of transcutaneous electrical nerve stimulation (TENS) in that MET uses far less current, but delivers the current in much longer pulses. Whereas TENS devices must be constantly worn because they offer virtually no residual effect, MET effects are long-lasting and cumulative.

The second category, represented by the application of the ear clip electrodes for anxiety, depression and/or insomnia control, is known as cranial electrotherapy stimulation, or CES.

Results in electro medicine are based on the design of the waveform, the amount of current (intensity), the location of the electrodes, and the amount of time it is used. The Alpha-Stim® 100 has 3 waveform generators; one for each channel and another common to both channels that serves to add random factors to avoid accommodation by the nervous system. The Alpha-Stim® 100 is actually a microcomputer, incorporating the latest advances in solid state electronics. All components are of the highest quality available to assure the user the ultimate in reliable and trouble-free performance. The output is accurate

within 0.1% under all operating conditions. The instrument's design assures electrical safety to the user by the use of readily available 9 volt batteries.

One important feature incorporated into the Alpha-Stim® 100 is an electronic circuit which operates to maintain a nearly constant current flow to the electrodes, minimizing the effects of electrode resistance variations due to poor electrode-to-skin contact.

The Alpha-Stim® 100 was developed by neurobiologist Dr. Daniel L. Kirsch and consultant engineers. Dr. Kirsch has been a leading pioneer in the field of electromedicine since 1972. He is board-certified in pain management by the American Academy of Pain Management and a Fellow of the American Institute of Stress.
Dr. Kirsch has served as Clinical Director of the Center for Pain and Stress-Related Disorders at Columbia-Presbyterian Medical Center in New York City and the Sports Medicine Group in Santa Monica, California. He lectures frequently to physicians worldwide on pain and stress management. Only original Alpha-Stim® products meet Electromedical Products International, Inc.'s exacting specifications.

ELECTROMEDICAL THERAPEUTICS

The application of electromedical currents is not a new concept. Ancients recognized the therapeutic value of naturally occurring electrical phenomena long before William Gilbert defined electricity in 1600. Both Aristotle and Plato refer to the Black Torpedo (electric ray fish) prescribed in 46 AD by the physician Scribonius Largus for the relief of a variety of medical conditions from headaches to gout (head to foot). In the 1800s dentists reported excellent results using crude electrical devices for pain control.

Experimentation with low intensity electrical stimulation of the brain was first reported by Drs. Leduc and Rouxeau of France in 1902. Initially, this method was called electrosleep as it was thought to be able to induce sleep. Research on using what is now referred to as cranial electrotherapy stimulation (CES) for treatment of anxiety, depression and insomnia began in the Soviet Union during the 1950s and continues through this day.

One hundred years ago, electrical devices were in widespread use to manage pain and claimed to cure a variety of medical disorders. Because of the unrefined early electrical technologies and political clout of the pharmaceutical lobbies, this form of therapy fell into disrepute by the medical profession in the early part of the 20th century. As a result, medical colleges stopped teaching electrotherapeutics. Biophysics was virtually eliminated from medical practice leaving chemistry as the master science and with it the burden of responsibility for curing all of mankind's ills. Now, at the turn of the 21st century, it is clear that chemistry as the sole explanatory model for medicine has not lived up to its promise causing modern medicine to re-examine the role of biophysics.

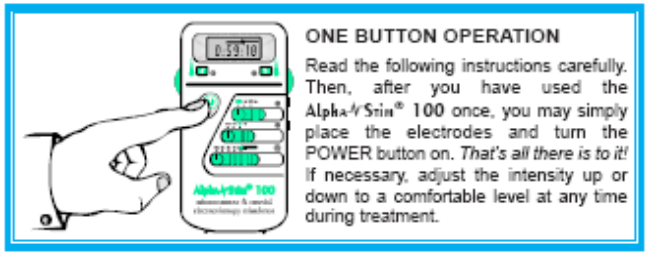
In 1965 Drs. Ronald Melzack of Canada and Patrick Wall of the United Kingdom published a paper explaining a new comprehensive theory of how pain is processed by our nervous systems. Their "Gate Control" theory also explained how electrical stimulation can influence the physiology of pain. By 1967 electrical devices were surgically implanted to control severe low back pain. Shortly thereafter, surface electrical units were used to test the person's response as a means of screening suitable surgical candidates. It was soon discovered that these surface electrical stimulators were equally effective and could be used for pain relief alone, avoiding surgery. Since then, these devices, known as transcutaneous electrical nerve stimulators (TENS), have become widely accepted by doctors and dentists to control many forms of pain. TENS technology is based on the concept of using electricity as a force. Repeatedly tapping a painful area with a blunt object, such as a pen or a spoon accomplishes the same thing. That is why TENS is sometimes referred to as ***counter-irritation analgesia***. There is virtually
no residual effect with TENS and the people who use it develop a tolerance to electrical stimuli that requires increasing the amount of current until it is ineffective at safe levels.

Modern science has established that there are extensive electrical fields at work in the body. The nervous system, for example, has long been known to work through both electrochemical and purely electrical signals. In fact, all molecules are held together by electrical bonding at the atomic level. This knowledge has led medical scientists such as Dr. Robert Becker of the USA and Dr. Björn Nordenström of Sweden (who served as Chairman of the Nobel Assembly) to propose completely new theories of physiology based on bioelectrical control systems.

Over the past few decades, technology has surpassed chemical analysis for the diagnostic side of medicine. With Alpha-Stim® technology, therapeutic intervention based on the new biophysics is finally emerging as a

viable alternative to pharmacological management and surgery. The original Alpha-Stim® Model 2000, a sophisticated clinical device, weighed 40 pounds and cost $5,850 US when it was first introduced in 1981. The Alpha-Stim® 100 microcurrent stimulator utilizes the most advanced technology available today. It is now possible, in most cases, to alleviate pain, anxiety, depression, and/or insomnia with far less current than traditional TENS uses, and experience long term and cumulative relief with as little as only a few minutes of treatment every other day. When used properly, we trust your new Alpha-Stim® 100 will help to control your pain, anxiety, depression, and/or insomnia and improve the quality of your life.

HOW TO USE THE ALPHA-STIM®100 FOR PAIN CONTROL


ONE BUTTON OPERATION
Read the following instructions carefully. Then, after you have used the Alpha-Stim® 100 once, you may simply place the electrodes and turn the POWER button on. That's all there is to it! If necessary, adjust the intensity up or down to a comfortable level at any time during treatment.

1. Clean skin - It is a good idea to clean the skin thoroughly around the treatment area before applying electrodes. Use mild soap and water and allow it to dry thoroughly. This is essential around areas where skin oils or dirt have accumulated, or where cosmetics or hair spray have been used.

2. Evaluate your pain - Don't forget to evaluate your pain before, from time-to-time during, and after each treatment. Your doctor can give you guidelines to help you do a quick, simple evaluation. This may consist of simply moving into a position that causes you to be more aware of your pain, then noting the level of pain you are experiencing on a 0 (no pain) to 10 (maximum pain) scale at the beginning and end of the treatment. Moving the affected body part through a range-of-motion and noting the increased range along with the decreased pain after treatment is also a good indicator of progress. Because the Alpha-Stim® works so fast in most people, it is necessary to use these reference parameters to determine effectiveness throughout a single treatment session. Keeping a daily (or even as often as hourly) chart of changes in your pain levels on a 0 to 10 scale will also assist your doctor in giving you the best possible advice. Consider 10 as "*the worst this condition has been*". To help you understand this system, a description of pain levels follows (use odd numbers for half values):

PAIN LEVEL DESCRIPTION

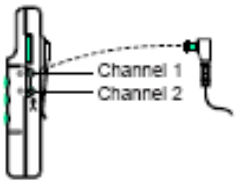
10 …… EXCRUCIATING, often debilitating.
8…… INTOLERABLE, concentration difficult, only able to perform undemanding tasks.
6…….DISTRESSING, but able to continue tasks.
4…..... DISCOMFORTING, may be ignored at times.
2…….MILD, only aware of it when attention is brought to it.
0…….NO PAIN.

It is also helpful to keep a record of the Alpha-Stim® treatment times with the frequency (Hz) and intensity (0 - 6 x 100 µA) settings (steps 5 - 7, below), along with the electrode locations you use.

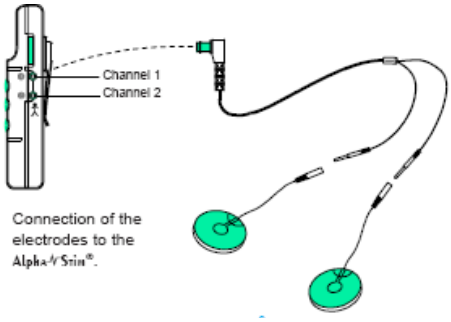
Some questions that will help you and your doctor understand your pain are:

*When did it start?
*Is there a position that lessens or increases it?
*Is there anything you can do to lessen or increase it?
*Does it feel deep under the skin or superficial?
*Are there any particularly sensitive spots you can point to with one finger?
*Is it always in the same place or does it move around?
*Are you having other symptoms which may be associated with your pain?
*How does it change throughout the day or week?
*What words describe it (such as burning, stabbing, aching, sharp or dull, superficial or deep, etc.)?

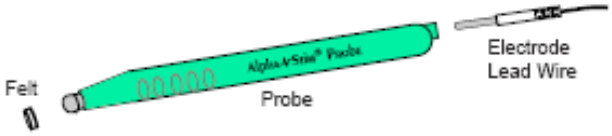
3. Connect wires to Alpha-Stim® 100
Insert the L-shaped plug of the electrode wire into the output receptacle on the Alpha-Stim®. The top receptacle is for channel 1, the bottom is for channel 2.



4. Attach probes or electrodes to wires - Insert the pin jacks directly into the probes, or into the wires coming off the self-adhesive electrodes. Push gently, but firmly into place for a good connection.

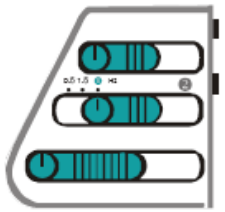


Probes
Two probes are included to stimulate through multiple electrode sites around your pain for brief, 10 second intervals at each location. One probe may also be used with a self-adhesive electrode, but 2 probes work best because they can more easily be moved around to achieve multiple angles of approach. A minute or 2 of probe treatment at various sites around the painful area is equivalent to about 10 minutes with the self-adhesive electrodes because the current is more concentrated through a smaller area. The electrodes for the probes are self-adhesive felts that must be saturated with Alpha Conducting Solution™ (ACS) to work. Discard the ring around the ACS bottle after opening to seal it tightly and prevent leakage. When using the probes, first clean and dry the probes, then attach the felts to the probes folding their edges down over the sides of the metal tip of the probes. Apply about 2 drops of ACS to each felt electrode. Re-wet the felts every 2 minutes or so.
Replace the felts with fresh ones before each new treatment session.

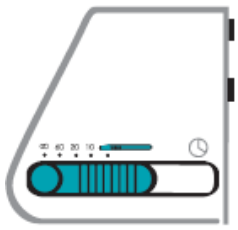


5. Set the frequency - Frequency refers to the number of pulses per second, measured in hertz (Hz). The frequency is set by adjusting the top 2 slide switches on the front of the unit. Generally, the only frequency you will ever need to use on the Alpha-Stim® 100 is 0.5 Hz. Sometimes 100 Hz is best for the initial treatment (first 30 seconds with probes, or 3 to 5 minutes with self-adhesive electrodes) of joint pain accompanied by inflammation (such as arthritis, bursitis, tendonitis, etc.). 1.5 Hz is more effective than 0.5 Hz in some people, but this is rare. *If both sets of electrodes are to be used at the same time, around the same area of the body, you must use the channel 1 setting on the channel 2 frequency control.* This control forces both channels to function in phase at the frequency set by the channel 1 frequency switch. *Failure to do this can cause interference between the channels and render the treatment ineffective*. Most people should just set channel 1 to the far left for 0.5 Hz, set channel 2 to the far right for the channel 1 setting, and leave them there.

Channel 1 Frequency set at 0.5 Hz


Channel 2 Frequency set at channel 1 setting

6. Set the timer - To change the timer slide the bottom switch on the front of the unit to the left or right. The amount of time needed to effectively manage your pain depends on the cause and severity of your pain, your overall health, and any ongoing physical or psychological stress that might make your condition worse. 10 or 20 minutes per self-adhesive electrode location is the recommended treatment time. Additional treatment time is usually not necessary, but will not do any harm. Some people will require 1 or more hours of treatment. The exception to this is that a few people have reported a return of their pain with excessive treatment. If this occurs wait a day or more (up to 1 week) before resuming treatment. When using the Alpha-Stim® 100 to manage pain more treatment time is not better! If the pain is fully relieved, it is best to stop treatment at that time and then repeat the treatment as necessary. Most people will realize a cumulative effect from Alpha-Stim® treatment. With continued use, you should see an increasing duration of relief between treatments. To prevent the recurrence of pain, the Alpha-Stim® 100 used every other day, or less, is actually more effective for most people than when used daily. However, some people will require initial and possibly ongoing daily treatments, and/or treatment for hours at a time. *The results you get determine what is best for you.*

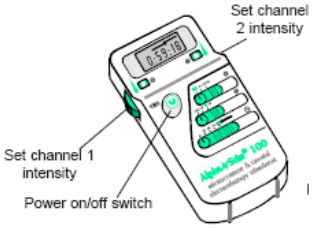

Timer setting at continuous (∞)

Timer displays 1 hour 23 minutes 45 seconds

Probe mode second cycle: stimulation off for 2 seconds

Probe made first cycle:stimulation on for 10 seconds

The display will count backwards with all timers except continuous (represented by the symbol ∞). Continuous counts forward to 99 hours, 59 minutes and 59 seconds before shutting the output off. The probe timer, on the right side of the switch, counts backwards for 10 seconds (9 - 0) while stimulating, then counts for 2 seconds (1 - 0) without generating any current, then repeats this cycle. This allows brief, 10 second treatments of the problem through many different angles and is preferred by most doctors who use the Alpha-Stim®. An audible beep at the end of the active 10 second cycle is your cue to move the probes. During the active 10 second cycle decide where you will move the probes next. If it takes more than 2 seconds to move them, because you are moving hair out of the way, or if you are rewetting the felts, ignore 1 beep. In fact, it is a good idea to also get into the habit of always ignoring the first beep so you don't have to even look at the LCD to determine an exact start time when using the probes.



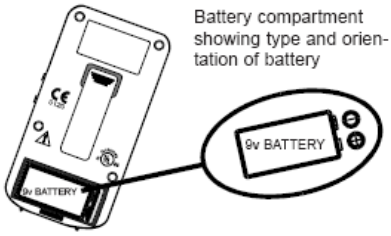
7. Set the intensity and turn power on - To change the intensity, use the dials located on both sides of the unit. The one on the left is for channel 1, the one on the right is for channel 2. The dial ranges from 0 to 6. Each number represents 100 microamperes (µA), 1 is for 100 µA, 2 is for 200 µA, etc. One microampere is one-millionth of an ampere, which is a measure of current. First make sure the intensity dials are set at a low level (no more than 2). Then turn the POWER on. The LCD will start to count down for all settings except continuous (∞). After placing your electrodes, turn up the intensity very slowly. Most people can take the full amount of current, but some people are more sensitive and must use a lower current. When used on the head, immediately decrease the intensity if a tingling feeling under the electrodes becomes uncomfortable, or if dizziness or nausea develops. This may happen while you turn up the intensity, or several minutes later. Decreasing the intensity will immediately relieve any of these unpleasant feelings and they are not necessary for optimal effect. Treat at 6 (600 µA) if possible. Because the Alpha-Stim® 100 uses such a low level of current, many people do not feel anything at all, even with the intensity set at the maximum level of 6. Do not be concerned if you can not feel the current - this is perfectly normal and your perception of the current will not effect the results. Once the power is turned on the timer setting will determine the amount of time the Alpha-Stim® 100 will remain in an active treatment mode. If a second set of electrodes are added while the Alpha-Stim® is running, the second channel will only provide stimulation for the amount of time remaining on the LCD.

Intensity of channel 1 set at 300 µA and intensity of channel 2 set at 500 µA

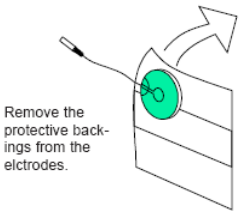
8. Check battery – Be sure you are using a good, fresh battery such as the one provided with the unit. Replace the battery when the display indicates the battery is low. Once the display indicates the battery is flat the Alpha-Stim® 100 will discontinue stimulation until a new battery is installed. **Do not use a rechargeable battery.**

Replace the battery when the display indicates the battery is low

All stimulation stops when battery flat symbol appears



9. Place electrodes - Where you place the probes or self-adhesive electrodes is the most important variable for optimum results. You must always use electrodes in pairs (if you are using both channels, you must use one pair for each channel). Peel the self-adhesive electrodes off of the protective backing and save the backing to store the electrodes after use. *If the adhesive is drying out and the electrodes do not stick well, you may wet the electrodes by wetting your finger with water and lightly rubbing it over the electrode for just 1 second (too much water will saturate them and actually shorten their life)*.



Discard and replace electrodes when adhesive has split or worn through to the conductive backing. Only use EPI AS-Trode™ brand silver electrodes available through your authorized Alpha-Stim® distributor. Some electrodes are as much as 20 times less conductive and will not allow the Alpha-Stim® current to penetrate the skin resistance.

Follow your physician's recommendations or use the following electrode placement guidelines:

There are only a few principles one must remember when treating pain with the Alpha-Stim® 100. You should be in a relaxed position to receive maximum beneficial effects. The most important variable is the position of the probes, or self-adhesive ASTrode ™ electrode pads.

Always place the probes -- or AS-Trode™ electrodes -- in such a way that if a line were drawn between them, that line would transect the problem area. Keep in mind that the body is 3- dimensional. Therefore, there will be many possible ways to draw a line through the problem. Some lines will work much better than others. *The correct electrode location is the one that works!* However, the one that works may be transient, working well one day, but ineffective another day. As the problem begins to resolve, the electrode locations may require constant adjustments.

When using the probes, remember that you have 2 seconds to move them between every 10 seconds of treatment. Hold the probes perpendicular to the skin and press firmly to insure good electrical conductivity. First treat in a large "X" manner over an area wider than the problem. An example of this would be to treat the whole back for back pain. This can be done by placing one probe on the right shoulder and the other on the left hip, followed by one on the left shoulder connected to the right hip. When appropriate, the entire head, arm, or leg is also treated first, before focusing in on the area of pain.

After the large “X”, treat at various angles closer in, and directly through the area of pain. An example of this strategy for knee pain would be to first make the large X by treating from the upper, and inner thigh down to the outside of the leg, near the ankle, then from the hip down to the inside leg near the ankle. Finish with smaller X's, or think of it as making a “star” closer in, directly around the knee. You will have to experiment until the best electrode locations are found. It is helpful to discuss this with your doctor initially, and again from time-to-time.

One treatment "set" is about 6 to 10 of these 10 second stimulation’s, each at a different angle of approach (*see sample protocols*). Therefore one set should only take about 2 minutes. Reevaluate your pain and range-of-motion between each set.

Think in terms of symmetry. Consider treating related areas located above, below, left, and right. Treat both sides of your body. This is essential in head and back problems, but treating the opposite side is also often helpful in arm and leg problems. Our natural tendency to protect a bad knee can cause problems to develop in the other knee. Treatment of the other "good" knee may be necessary to get any results or to increase the longevity of the results. Then it is helpful to connect the 2 knees. This is done by putting one of the probes or pads from a single channel on each knee, and moving them around to a few different places.

Often the pain will migrate as a response to therapy. Follow it. Use the same treatment strategy described above for the pain's new location. In some very rare cases, the treatment may initially increase pain temporarily. If the pain does increase, continued treatment will usually produce good results. An increase in pain is most likely due to the treatment’s effects on the body’s compensation for the pain. For example, a weakness of the muscles on one side of the back often results in a tightness on the opposite side. If the tighter muscles are causing the pain, and treatment is concentrated solely on the area of pain, the other side will find other ways to compensate. That is why it is always best to treat a broad area around the pain.

Do not place the electrodes too close together. For example, one right next to each side of the spine is not a good placement for back pain. In this 2-dimensional example the current will travel just under the surface of the skin to the other electrode and not penetrate to the area requiring treatment. Here it would be better to put one probe next to the spine and the other on the opposite side of the body, on the side, near the front. Then move the probes to the other side after 10 seconds. Another possible electrode placement for back pain is to place one on each side of the body (between the shoulders and the hips) at the level of pain.

Silver AS-Trode™ Self-Adhesive Electrodes

These are used following the same strategy as the probes, except longer. For optimum results, silver AS-Trode™ electrodes must also be moved around the problem area. Whereas the probes may be used for 10 seconds a site, an equivalent procedure using AS-Trode™ electrodes is to leave them at each location for at least 5 to 10 minutes.
Some people require a full hour or more of stimulation daily. Accordingly, AS-Trode™ electrodes are necessary. However, if brief stimulation works, do not continue treatment. *Remember, more is not better when using* Alpha-Stim® *technology!* Treating briefly with the probes is also a good way to determine optimal placement locations for longer treatment with the self-adhesive
AS-Trode™ electrodes.

When To Stop

When using the probes, reevaluate your pain using the 0 to 10 scale after a few 2 minute treatment sets. For some simple problems, it is preferable to reevaluate after each set. Use the original criteria. Stop when the pain is completely gone, or when the improvement has reached a plateau after several treatment sets. Continuing to treat the area at this time may cause the pain to return! If the pain is gone, it is far better to stop treatment for that day *even if you only had 2 minutes of treatment.*

If you can no longer identify any pain, but feel stiff, this indicates that it is time to stop treatment for the day. The Alpha-Stim® will not reduce residual stiffness. Usually post-pain stiffness will wear off by itself.

Although most people will have an immediate response to treatment, in some the effects will be delayed, continuing to improve over a day or 2 after the treatment. In these people, relief will generally occur 1 to 3 hours after treatment or even as late as the next morning. Some people will experience a combination effect, continuing to improve over time. People who experience a delayed effect are more difficult to treat due to lack of immediate feedback which helps to determine the best electrode locations. Usually, people who experience a delayed effect from Alpha-Stim® treatment also have a delayed effect with anesthetics. If your dentist had to wait more than 10 minutes after injecting anesthetic prior to doing dental procedures, you may have a delayed effect from Alpha-Stim® treatment. A treatment diary is helpful in analyzing your progress if you have a delayed effect.

Follow-Up

Most people should try at least 5 treatments before evaluating their response to Alpha-Stim® 100 therapy. It helps to understand that the effects are cumulative. Like antibiotics and most other drugs, one must take several doses over a period of time to get results. Although results will usually be seen during or subsequent to the first treatment, the longevity of the results can only be evaluated after a series of treatments. In some cases the results will plateau to a similar time period regardless of treatment. For example, you may only get 2 days of relief no matter what combination of treatment strategies are employed. In some cases of severe pathology, the effectiveness may only be short-lived.

Tips For Limited Or Poor Results

While the Alpha-Stim® 100 is significantly efficacious when it is used correctly (greater than 25% improvement in signs and symptoms) in at least 90% of the people who use it for pain, anxiety and depression, and 80% for insomnia, it will not work for everyone. However, if pain relief is not immediate, consider treating the primary area of pain at a lower intensity setting of 1 - 2 (100 to 200 µA) with AS-Trode™ electrodes for 60 minutes or more. If necessary, it can be used all day. 1.5Hz may produce better results in some people when the 0.5 Hz fails, but this is rare. It may also be necessary to treat all areas of pain anywhere on the body in order to get results. Finally, If the Alpha-Stim® 100 is not working well for you, contact Alpha-Med, your local authorized Alpha-Stim® distributor for technical support.

10. Turn power off - When using the continuous or probe timers you must turn the power off after use to avoid a slight drain on the battery. At the end of the 10, 20, and 60 minute timers the Alpha-Stim® 100 will turn itself off automatically.

11. Disconnect and Remove Electrodes - Carefully replace the electrodes on their protective backing and put them back in the sealable bag they came in. If you are keeping a diary, record your pain level now and note the time interval until the pain returns.

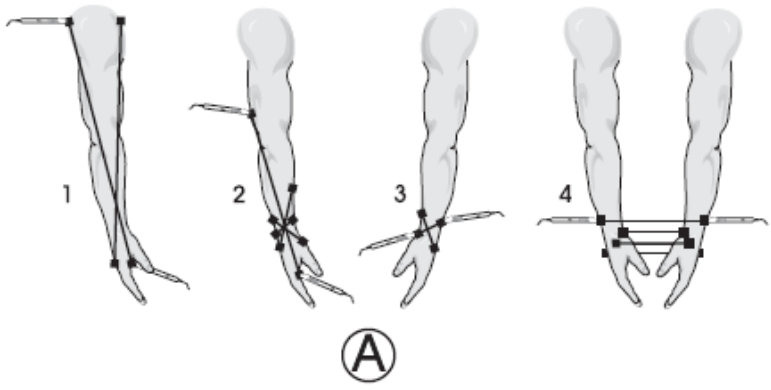
SAMPLE PROTOCOLS

The following sample protocols are guidelines for Alpha-Stim® treatment. These are actually examples of the same strategy applied to different parts of the body. Total treatment times are provided for 10 second probe applications and are estimated based on the maximum treatment time to complete one set of probe applications for a given area. In actual practice, one set of probe treatments will average about 2 minutes. Although it takes considerably longer with self-adhesive ASTrode ™ electrodes, the same strategy applies for determining where to treat.

Keep in mind that the strategy is to visualize a line between the probes going right through the part of your body in pain. 2-dimensional illustrations are not an adequate substitute for 3-dimensional people. Place the probes on opposite sides of the body, such as front and back for back pain. As in every other area of life, there is a learning curve. Be creative, and have fun with your new and powerful tool to keep your pain under control.

Remember to rate your pain on a 0 - 10 scale before, and every 1 or 2 minutes throughout the treatment with the probes. Stop when your pain is gone, or if it has decreased, but you do not feel any further improvement after an additional 2 minutes of using the probes. Also note improvement in range-of-motion and any other signs and symptoms.

It is almost always best to use the Alpha-Stim® at 0.5 Hz, at the maximum comfortable intensity (usually 6 for the probes). Wet the felt electrodes frequently using Alpha Conducting Solution™. If AS-Trodes™ are used for an extended period of time (more than 1 hour), use a minimum amount of current, but not less than 1 (100 µA).
Augmenting the pain treatment with CES (by the application of the ear clip Electrodes) directly following the pain treatment can reinforce and prolong the
effects of a pain treatment.



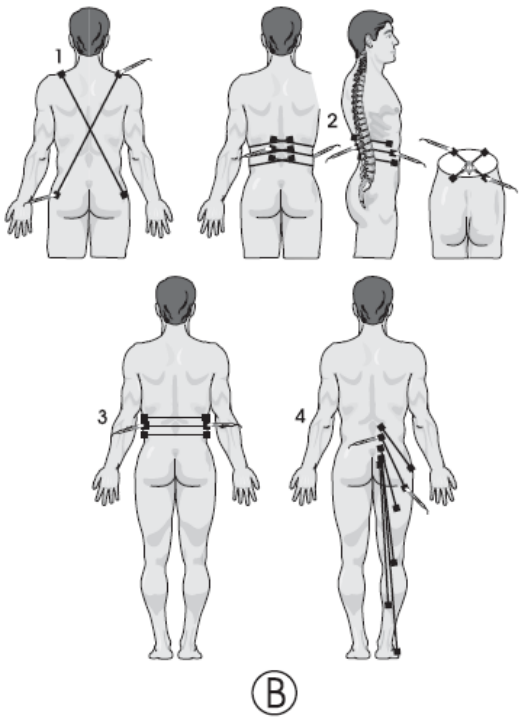
Example A: ARM PAIN

1. Make a large “X” by treating from the front of your shoulder to the back of your hand, and the back of your shoulder to the front (palm) of your hand. 20 seconds.

2. Complete 40 seconds to 1 minute of smaller “X’s” closer in directly around the shoulder, elbow, wrist, hand, or other area of pain. For carpal tunnel syndrome (CTS) or repetitive strain injury (RSI), treatabove the elbow to the webs between the fingers in addition to local treatment at the wrist.

3. Treat the area corresponding to the area of pain on the opposite arm for 20 to 40 seconds.

4. Connect your two arms by placing one probe on each in several symmetrical places encompassing the painful area for 40 seconds to 1 minute.



Example B: BACK PAIN

1. Make the big “X” by treating from the top of your right shoulder to your left hip or low back, then connect your left shoulder to your right hip or low back. 20 seconds.

2. Place one probe about 2 cm next to the spine (center of your back)at the level where your pain is, and the other on the opposite side, on the front, near your side. Reverse the sides to make a horizontal “X”. Repeat the procedure by making another

horizontal “X” above and another “X” below the problem. 1 minute.

3. Treat across your back, from each side of the body through the painful area, then again, slightly above and below it. 30 seconds.

4. If you have low back pain radiating down your leg, connect various areas around your low back about 2 cm from your spine (center of back), with your leg at 10 - 15 cm intervals with the last, furthest placement at the outside of your foot (or just past where the pain radiates to).

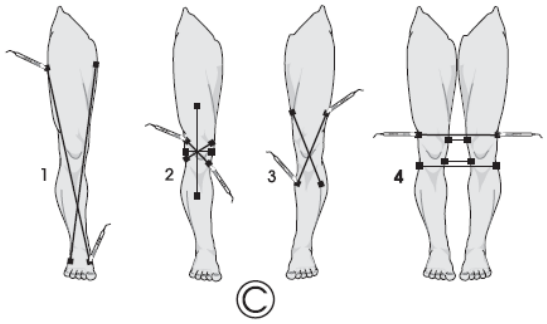
Example C: LEG PAIN

1. Make the large "X" by treating from your upper, inner thigh to the outside of your foot, then from your hip to the inside of your foot. 20 seconds.

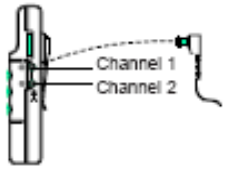
2. Complete 40 seconds to 1 minute of smaller "X's" closer in directly around your hip, knee, ankle, foot, or other area of pain.

3. Treat the area corresponding to the area of pain on the other leg. 20 seconds.

4. Connect the two legs by placing one probe on each in several symmetrical places encompassing the painful area. 40 seconds.



HOW TO USE THE ALPHA-STIM® 100 FOR ANXIETY, DEPRESSION AND/OR INSOMNIA CONTROL



1. Clean skin - Clean the skin of your ear lobes thoroughly and allow them to dry before applying electrodes. Use mild soap and water or baby wet wipes.

2. Connect ear clip electrodes to Alpha-Stim®100 - Insert L-shaped plug from the ear clip electrodes into either of the two output receptacles on the Alpha-Stim® 100. The top receptacle is for channel 1, the bottom is for channel 2.

3. Attach ear clip electrode pads to ear clips – First clean and dry the ends of the ear clips, then peel 4 self-adhesive ear clip electrode pads off of their protective backing and attach them to the inside of each ear clip electrode (as originally packed). Replace ear clip electrode pads after each treatment. If using the Alpha-Stim® 100 in a clinical setting, clean the clips thoroughly with alcohol prior to replacing the ear clip electrode pads between patients.

4. Wet electrodes - Wet each of the 4 earclip electrode pads while attached to the ear clips with about 2 or 3 drops of Alpha Conducting Solution™ (ACS). Discard the ring around the ACS bottle after opening to seal it tightly and prevent leakage.

5. Place electrodes on ears - Clip electrodes on each ear lobe close to the jaw, and as high on the lobe as possible. You must always use both clip electrodes to complete the electrical circuit.

6. Set the timer - 20 to 60 minutes is recommended unless otherwise specified by your physician. People who can only tolerate an intensity setting of 2 (200 microamperes) or less will generally need more than 20 minutes.

7. Set the frequency - Always use 0.5 Hz when using the ear clip electrodes.

8. Set the intensity and turn power on - Be certain the intensity control is all the way down to 0. Turn power on. The LCD will start counting down. Turn intensity up slowly until a comfortable tingling feeling is felt (for some people it is normal not to feel anything). Immediately decrease the intensity if the tingling feeling becomes uncomfortable or if dizziness or nausea develops. Decreasing the intensity should immediately relieve any of these unpleasant feelings and they are not necessary for optimal effect. Some people experience a feeling of “heaviness” during the early part of treatment. If this occurs, treatment should be continued until at least 2 minutes after this feeling “lifts”, and a lighter feeling is experienced, even if it takes more than 60 minutes.

9. Check battery - Be sure you are using a good, fresh battery such as the one provided with the unit. Replace the battery when the display indicates battery low . Once the display indicates battery flat the Alpha-Stim® 100 will discontinue stimulation until a new battery is installed. Do not use a rechargeable battery.

10. Relax - Sit or lie down and let the Alpha-Stim® 100 relax you.

11. Automatic Power off - At the end of the timed cycle the power will turn off automatically.

12. Disconnect and remove ear clip electrodes - Use daily for the first 2 weeks, then 3 times per week or as directed by your physician.

SKIN CARE

1. Apply electrodes on dry, clean unbroken skin only.
2. Before applying and after removing electrodes, wash skin with mild soap and water or clean with baby wet wipes. Rinse and allow to dry completely.
3. Excess hair at the electrode site should be clipped, but not shaved.
4. If skin irritation develops discontinue use and consult your physician.

WHAT TO EXPECT

Pain and/or anxiety reduction is usually experienced during a treatment, but may be felt hours later, or as late as 1 day after treatment. Depression and/or insomnia control is generally felt after 1 to 3 weeks of daily treatment. After the condition is under control, use of Alpha-Stim 3 times per week is usually sufficient to maintain good results.

The Alpha-Stim® 100 leaves the user alert while inducing a relaxed state. One 20 minute session is usually all that is needed to effectively control anxiety, depression and/or insomnia for at least a day. It may also be used as an adjunct to medication and/or psychotherapy. For people who have difficulty falling asleep, Alpha-Stim® should be used at least 3 hours before going to bed or the increased alertness may interfere with sleep.

After treatment, there are usually no physical limitations imposed so most people can resume normal activities immediately. Some people may experience an euphoric feeling, or relaxation that may temporarily impair their mental and/or physical abilities for the performance of potentially hazardous tasks, such as operating a motor vehicle or heavy machinery for up to several hours after treatment.

At present, there are over 125 research studies on using cranial electrotherapy stimulation for anxiety, depression and/or insomnia related disorders in humans and 29 animal studies. No significant lasting side effects have been reported. Occasional self-limiting headache, discomfort or skin irritation under the electrodes, or lightheadedness
may occur. If a heavy feeling occurs, continue treatment until at least 2 minutes after it gives way to a light feeling. Some people will see flashing lights due to stimulation of the optic nerve. Some may experience the metallic taste of dental fillings. Neither of these conditions are harmful.

PRESCRIBING INFORMATION

CE Conformity Statement for Europe: The Alpha-Stim® 100 is a Class IIa, Type B medical device. It has been independently tested by outside agencies to provide assurance of conformity to applicable standards for medical equipment safety and electromagnetic compliance.

Caution Statement: Outside of the USA, this device is available world wide without a prescription but consultation with a qualified health care professional is recommended for difficult and unresponsive problems or when used in conjunction with pharmaceuticals or other therapeutic intervention.

Indications: Alpha-Stim® 100 cranial electrotherapy stimulation (CES) technology is continuously being subjected to rigorous study and evaluation by the international medical community. Findings to date indicate that the Alpha-Stim® 100 is an effective treatment with broad applications for a variety of syndromes involving pain and for the management of anxiety, depression and/or insomnia or for the short term relief of the symptoms of pain, of anxiety, depression and/or insomnia. In many cases it is the sole therapeutic method required. Effective results in pain management have been seen during and/or subsequent to stimulation over effected body parts, adjacent areas and areas distant from those in pain. As with any therapeutic intervention, not all people will respond to the Alpha-Stim® 100. The degree of efficacy will vary with the nature of the problem being treated and the overall health of the person and with the method of the treatment.

Contraindications: Alpha-Stim® 100 may affect the operation of cardiac pacemakers (particularly demand type pacemakers). Do not stimulate directly on the eyes, or over the carotid sinus (upper side of neck, below the ear and behind the jaw).

Precautions: For external use only. Do not allow children to use or handle this device without adult supervision. Do not operate potentially dangerous machinery or vehicles during, and in some cases, for several hours after treatment. Caution is advised in cases where other forms of analgesia (pain control) would not be used, such as to retain the beneficial aspects of pain for diagnosis or in cases where people may overuse pain controlled areas. Safety of stimulation has not been established during pregnancy. There have been isolated reports of blood pressure being lowered by CES, so care should be taken while using the Alpha-Stim® 100 with high blood pressure medication.

Adverse Effects: Adverse effects are usually mild and self-limiting. Adverse effects seen in approximately 4,541 patients in controlled, open, uncontrolled conditions, and by physician survey and reasonably associated with the use of CES are dizziness (6 cases, 0.13%), skin irritation/electrode burns (5 cases, 0.11%), and headaches (9 cases, 0.20%). Prolonged CES treatment at higher than necessary currents may cause dizziness or nausea that can last for hours to days. Treatment immediately prior to going to sleep may cause difficulty sleeping due to increased alertness. It is recommended that CES be used at least 3 hours before going to sleep. Paradoxical reactions such as hyperexcited states, increased anxiety, and sleep disturbances may occur.

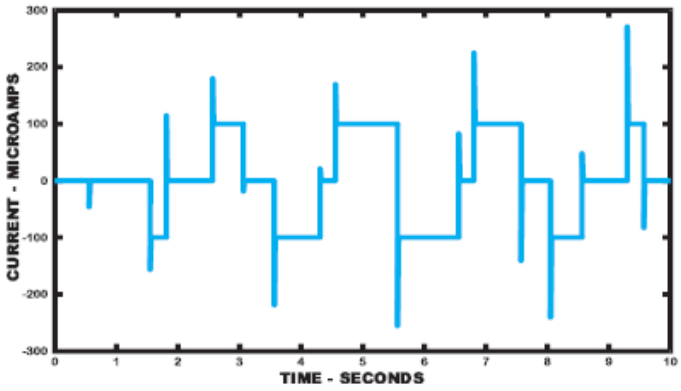
If the Alpha-Stim® 100 does not control your pain, anxiety, depression and/or insomnia within 3 weeks, consult your physician.

TECHNICAL SPECIFICATIONS

Electrical

Power Source	One 9 volt battery (included). Replace with disposable batteries (alkaline preferred). Do not use rechargeable batteries.
Timer Settings	Probe (10 seconds on alternating with 2 seconds off), 10, 20, 60 minutes, and continuous ( )
Current	10 to 600 µA continuously adjustable
Frequency	0.5, 1.5, or 100 Hz (pulses per second)
Waveform	Bipolar asymmetric rectangular waves, 50% duty cycle, 0 net current (see graphic depiction)

Alpha-Stim® 100 Waveform



Mechanical

Height	13.5 cm
Width	6.4 cm
Depth	3.3 cm
Weight	156 gm with battery

Carrying Case

Height	20.8 cm
Width	26.9 cm
Depth	4.6 cm
Shipping Weight With Unit	0.91 kg

Accessories

The Alpha-Stim® 100 is packaged complete with one set of 4 self-adhesive AS-Trode™ brand silver electrodes (good for approximately 2 weeks to 1 month of use), electrode wires, 2 probes, ear clip electrodes, 256 earclip electrode pads, 100 probe electrode pads, a 15 ml bottle of Alpha Conducting Solution™ (ACS), a 9 volt battery, carrying case, and illustrated Owner's Manual. This is everything necessary to begin to use the Alpha-Stim® 100 right away. Replace conducting solution, self-adhesive and earclip electrode pads only with authorized Alpha-Stim® and AS-Trode™ brand products.

STORAGE AND CLEANING

Remove the battery when storing the Alpha-Stim® 100 for an extended time (more than 1 month). Always use the carrying case to transport the Alpha-Stim® 100. When not in use, the Alpha-Stim® 100 and all its accessories should be stored in the carrying case provided. The Alpha-Stim® 100, and its accessories, should be stored and used within a temperature range between 0° and 36°C, with a relative humidity of 90% or less, at an atmospheric pressure between 0.9 - 1.1 atm. Clean the Alpha-Stim® 100 by periodically gently wiping the surface with a damp cloth when dirty. Use mild soap and water. Use of other cleaning solutions may damage the case. Never spray cleaners directly on to the device. 70% isopropyl alcohol may be used on the probes and clip electrodes to disinfect them between treatments.

TROUBLE SHOOTING SERVICE

PROBLEM	POSSIBLE SOLUTIONS
There is no sensation of current.	Note: This is normal for some people. Try turning up the intensity or wetting electrodes.
There are no results.	Vary the electrode locations. Also treat all other areas of pain. Try 1.5 Hz, or 100 Hz, if 0.5 Hz is ineffective. Treat more often and/or for a longer time at a lower intensity. Try 5 to 10 treatment sessions. Consult your doctor.
Electrodes do not stick well.	Replace AS-Trode™ electrodes. Apply felt electodes to a clean, dry surface.
Probes do not conduct current.	Use more Alpha Conducting Solution™.
There is no output.	Change the battery if the "battery low" or "battery flat" symbols appear. Try turning up the intensity. Check lead wires and electrodes: make sure all connections are firmly in place.

SERVICE

The Alpha-Stim® 100 is not user serviceable.

To obtain service, first contact Alpha-Med -your authorized Alpha-Stim® distributor for advice or a return authorization number (RAN). Upon authorization by Alpha-Med, you may send the entire unit, with all accessories and packed in the original carrying case, to Alpha-Med by registered mail or delivery, insured and freight prepaid. Please include a copy of your invoice and a note describing the problem. Please do not forget to include your return address, your phone number, and if available, your fax number and email address.

5 YEAR LIMITED WARRANTY

While in the opinion of Electromedical Products International, Inc., ("EPI"), the manufacturer of Alpha-Stim devices, the Alpha-Stim® 100 ("product") is generally effective in relieving pain, anxiety, depression and/or insomnia, health care is not an exact science and individual results will vary. Accordingly, EPI makes no warranties as to the effectiveness of its products for a given individual. Electromedical Products International, Inc. warrants to the original purchaser (and no one else) that each new Alpha-Stim® 100 is free of defects in workmanship and materials, under normal use, for a period of 5 years from original purchase date, except for accessories. The warranty registration card must be completed and returned to Alpha-Med in order to validate the
warranty.

Accessories such as batteries and electrodes are excluded from the warranty and are sold "as is" because they may be easily damaged before or during use. During the warranty period, EPI's sole obligation shall be, at EPI's option, to replace or repair the Alpha-Stim® 100 without charge. In order to recover under this warranty, purchaser must first contact Alpha-Med, your authorized Alpha-Stim distributor, by phone, mail, fax, or email for a return authorization number (RAN). Purchaser must have an original copy of the invoice to prove that the product is still covered by warranty. The authorized return may then be shipped to Alpha-Med, safely packaged with all accessories, packed in the original carrying case, by registered mail or delivery, insured and freight prepaid. Alpha-Med and EPI will not be responsible for damage due to improper packaging or shipment. If EPI determines there is a defect covered by this warranty, the repaired or replaced product will be shipped back, freight and insurance prepaid, as soon as reasonably possible. If EPI determines in its sole discretion that the product does not contain defective workmanship or materials, EPI will return the product and the return freight and insurance charges shall be the purchaser's responsibility.

This warranty is voided immediately if the product has been subjected to abuse, accidental damage, damage in transit, negligence, acts of nature, or damage resulting from failure to follow operating instructions, or alteration/disassembly by anyone other than by EPI.

Electromedical Products International, Inc. and Alpha-Med shall not be liable for any direct, indirect, special, incidental, or consequential damages, lost profits or medical expenses caused by any defect, failure, malfunction, or otherwise of the product, regardless of the form in which any legal or equitable action may be brought against EPI or Alpha-med (such as contract, negligence, or otherwise). In no event shall EPI's or Alpha-Med's liability under any cause of action relating to the product exceed the purchase price of the product.

Manufactured by:

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